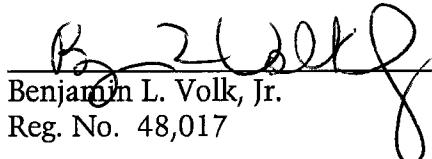


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Reg. No. 48,017

In re application of :
Ewing B. Gourley
Serial No.: 09/710,227 : Examiner: Porter, Rachel L.
Filed: November 10, 2000 : Group Art Unit: 3626
For: Method and Apparatus for Processing :
Pharmaceutical Orders to Determine Whether :
A Buyer of Pharmaceuticals Qualifies for an :
"Own Use" Discount :
:

Reply Brief

In response to the Examiner's Answer dated May 2, 2008, Applicant submits the following as its Reply Brief in connection with the appeal of the above-referenced patent application.

At page 42, the Examiner's Answer alleges that various arguments from the Appeal Brief which are based on a distinction between "retail pharmacies" and "closed pharmacies" are not pertinent to the patentability of the claims. (See, e.g., Amended Appeal Brief; p. 5-6; 21-25).

In response to applicant's arguments that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., distinction between closed pharmacies and retail pharmacies) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. (See Examiner's Answer; p. 42).

Applicant strongly disagrees. Independent claims 1, 30, and 62 specifically require that a retail pharmacy be involved as a buyer.¹ Applicant respectfully submits that the claim limitation "retail pharmacy", even when given its broadest reasonable meaning, cannot be reasonably interpreted to mean a "closed pharmacy". The term "closed pharmacy" is defined by Applicant in the specification as follows:

A ***closed pharmacy*** is a pharmacy that supplies pharmaceuticals to institutions such as hospitals or nursing homes, ***but does not sell pharmaceuticals to walk-in customers.*** (See Patent Application; p. 3, lines 11-13 (emphasis added)).

Thus, the term "closed pharmacy" specifically excludes a pharmacy that sells pharmaceuticals to walk-in customers. By contrast, Applicant respectfully submits that the claim limitation "retail pharmacy" must be interpreted at least in part to require that the retail pharmacy sell pharmaceuticals to walk-in customers. Such an interpretation is consistent with the usage of the term "retail pharmacy" in the specification. (See Patent Application; p. 3, lines 21-22 (noting that retail pharmacies "also supply pharmaceuticals to walk-in customers")). As such, Applicant respectfully submits that any interpretation of the claim limitation "retail pharmacy" by the Examiner which would encompass a "closed pharmacy" is inappropriate because such an interpretation would be repugnant to its ordinary meaning and inconsistent with the usage of those terms in the specification.

Moreover, Applicant respectfully submits that this misunderstanding of the terms "retail pharmacy" and "closed pharmacy" by the Examiner is directly related to the Examiner's failure to recognize the patentability of independent claims 1, 30, and 62 over the cited

¹ For example, independent claim 1 specifically recites that the buyer comprises "one from a group consisting of (1) an entity comprising at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (2) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home". Independent claim 30 specifically recites that the software executed by the processor be configured to "confirm whether said buyer is any of a group consisting of (a) an entity comprised of at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home, and (b) at least one retail pharmacy that supplies pharmaceuticals to at least one nursing home". Independent claim 62 specifically recites that "said buyer comprises at least one selected from the group consisting of (1) a retail pharmacy that supplies pharmaceuticals to at least one hospital, nursing home, or long term health care facility where said at least one patient resides, and (2) an entity comprising a plurality of said retail pharmacies".

references. Page 3 of the patent application provides background information as to the problem solved by the invention of claims 1, 30, and 62.

Currently, in the United States ..., approximately 55% of nursing homes purchase their pharmaceuticals from "closed pharmacies." A closed pharmacy is a pharmacy that supplies pharmaceuticals to institutions such as hospitals or nursing homes, but does not sell pharmaceuticals to walk-in customers.

Because these closed pharmacies have an exclusive customer list of customers who are eligible to buy pharmaceuticals at an "own use" discount, pharmaceutical manufacturers are willing to sell pharmaceuticals to these closed pharmacies at a discounted price. That is, pharmaceutical manufacturers are not overly worried that the "closed pharmacy" will sell discounted pharmaceuticals at a regular price to customers ineligible for a discount, because the "closed pharmacy" has virtually no such customers.

However, approximately 45% of nursing homes are served by retail pharmacies. These retail pharmacies, in addition to supplying the pharmaceutical needs of a nursing home, also supply pharmaceuticals to walk-in customers. Thus, when a retail pharmacy purchases drugs from a pharmaceutical manufacturer or a pharmaceutical distributor, the retail pharmacy may be purchasing pharmaceuticals on behalf of not only the nursing home, but also its walk-in customer trade. ***Because these retail pharmacies are supplying pharmaceuticals to walk-in customers as well as nursing homes, pharmaceutical manufacturers have been unwilling to sell "own use" discount pharmaceuticals to such retail pharmacies for fear of diversion.*** ... As a result, some 7,648 nursing homes (approximately 45% of all nursing homes) pay more money than necessary when purchasing pharmaceuticals. (See Patent Application; p. 3, line 9- p. 4, line 2 (emphases added)).

Against this backdrop, Applicant asserts that the pharmacies described in the Colella reference are not retail pharmacies, but rather "closed pharmacies". This is apparent from the Colella reference when it explains the problem its system seeks to solve:

It has been known for health care providers, such as hospitals, to have a ***pharmacist or pharmacy department within the hospital*** to coordinate the dispensing of drugs to the patients of the health care institution. The pharmacists ***in such health care institutions*** have long been burdened with the increasingly complex record keeping and inventory management that results from hospitals caring for hundreds, if not thousands of patients every day. (See Colella; col. 1, lines 12-20 (emphasis added)).

Thus, Applicant respectfully submits that a person having ordinary skill in the art who reads the Colella reference would understand that Colella's "pharmacy department within the hospital" is a "closed pharmacy" (meaning that the in-hospital pharmacy would not serve the

pharmaceutical needs of walk-in customers). To alleviate the inventory management and record-keeping burdens for such closed pharmacies, Colella discloses a distributed system for tracking pharmaceutical usage within a hospital and leveraging this usage tracking to stay current on assembling orders for new pharmaceuticals to refill the pharmacy shelves. No aspect of Colella addresses the distribution of pharmaceuticals to walk-in customers. For example, Applicant finds no disclosure in Colella of a system that would track distributions of pharmaceuticals to walk-in customers. Thus, when the Examiner's Answer contends that Colella discloses processing pharmaceutical orders for a buyer, wherein the buyer comprises a retail pharmacy or an entity comprising at least one retail pharmacy (see Examiner's Answer at p. 6), Applicant respectfully submits that this assertion is completely erroneous.

Most telling, Colella in no way addresses the concept of placing orders for pharmaceuticals for which the price is reduced by an "own use" discount. Applicant respectfully submits this silence further confirms the fact that Colella addresses closed pharmacies within hospitals for which no question exists in the minds of pharmaceutical sellers as to their entitlement to the "own use" discount.

Moreover, the Gardner reference that is relied upon by the Examiner for teachings relating to the "own use" discount actually teaches hospitals to monitor their pharmacy practices to ensure that brokers and business enterprises which serve retail pharmacies such as "small drugstores" do not receive "own use"-discounted pharmaceuticals from the hospital's inventory. Thus, Applicant respectfully submits that Gardner teaches away from the invention defined by claims 1, 30, and 62 because Gardner teaches the use of monitoring and auditing practices that are designed to prevent "own use"-discounted pharmaceuticals from ever reaching retail pharmacies.

In stark contrast, the invention defined by claims 1, 30, and 62 constitutes a new, useful, and nonobvious invention that conducts an audit on a buyer's pharmaceutical needs to make it possible for "own use"-discounted pharmaceuticals to reach retail pharmacies – a result that Gardner seeks to avoid and that Colella has no capability of achieving.

The Examiner's Answer also repeatedly mischaracterizes the arguments in Applicant's Appeal Brief as attacking the cited references individually rather than the prior art combination as a whole. (See Examiner's Answer; e.g. at p. 40, 41, and 43). However, Applicant's

arguments on appeal do in fact address the asserted prior art combination as a whole. These arguments establish that the Colella and Gardner references, when considered in combination as a whole, would lead a person having ordinary skill in the art to employ Colella's pharmaceutical inventory monitoring and management system to audit a closed pharmacy's practices to detect whether any pharmaceuticals within that closed pharmacy's inventory (which have presumably already been purchased at an "own use" discount) are being diverted to questionable brokers/business enterprises. Thus, the prior art combination cited by the Examiner addresses a post-purchase audit of pharmaceuticals which have already received an "own use" discount to assess whether those pharmaceuticals are being diverted to questionable brokers/business enterprises. By contrast, the invention defined by independent claims 1, 16, 30, 62, 69, 75, and 76 addresses a pre-purchase audit of a pharmaceutical purchase order to assess whether that purchase order qualifies for an "own use" discount. Such an invention is not rendered obvious by the Colella/Gardner reference, as explained in the Amended Appeal Brief.

With respect to other comments found in the Examiner's Answer, Applicant notes the following:

- As to the rejection of claim 69 under 35 USC 112, first paragraph, Applicant notes that the Examiner's Answer fails to address any of the case law cited by Applicant in the Amended Appeal Brief. The Examiner's rejection of claim 69 is predicated upon the Examiner's interpretation of the claim term "a computer configured to ..." as a "means plus function" limitation. Rather than responding to Applicant's citation and discussion of specific case law addressing the use of the term "computer" in a claim, the Examiner's Answer mistakenly relies on case law from the biotechnical field where the claim term "computer" was not involved. As such, for the reasons expressed in the Amended Appeal Brief, Applicant respectfully submits that the rejection of claim 69 is erroneous.
- With respect to the rejections of claims 37, 43, and 44 under 35 U.S.C. 112, second paragraph for indefiniteness, Applicant notes that the Examiner's Answer fails to address any of the case law cited by Applicant in

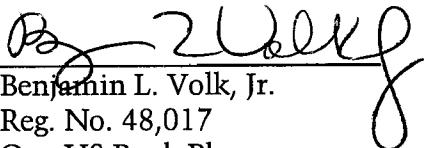
the Amended Appeal Brief in which the use of a relative term such as "sufficient" was not found indefinite because of the guidance provided in the specification as to the meaning of such a term. In the Amended Appeal Brief, Applicant pointed out specific passages in the specification that provide an understanding to one of ordinary skill in the art as to what would be a "sufficient number of matches." (See Amended Appeal Brief; p. 14-16). The Examiner's Answer fails to address the specific paragraphs of the specification cited by Applicant and instead has merely repeated the unsupported conclusion that "the specification does not provide a standard." (See Examiner's Answer; p. 39).

Thus, for the reasons expressed herein and in Applicant's Amended Appeal Brief, Applicant respectfully submits that the Examiner's rejections as to all pending claims in this patent application are in error and must be reversed. Favorable action is respectfully requested.

Respectfully submitted,

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